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Development of a Nutrition Assessment Tool for Stroke - NATS Study

Submission date
21/09/2011

Recruitment status
No longer recruiting

Registration date
18/11/2011

Overall study status
Completed

Last Edited
18/03/2016

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The importance of nutrition on health status and recovery from acute illness is reflected by the NICE guidelines Nutrition Support in Adults (http://guidance.nice.org.uk/CG32/PublicInfo/pdf/English). Stroke patients are at particular risk from malnutrition which is associated with poor outcomes and slower rate of recovery. Between 30% to 90% of all adults and children were found to have lost weight during their hospital admission partly because malnutrition is often unrecognised and untreated. There are many risk factors specific to stroke which can increase malnutrition e.g. dysphagia (impaired swallowing), dysphasia (impaired language), appetite loss, taste disruption, dependence on assisted feeding, cognitive impairment, reduced mental capacity, dominant versus non-dominant weakness etc. (in addition to general factors.) In spite of the specific needs of stroke patients, research within the evidence base appears to focus on a small number of individual risk factors e.g. difficulty swallowing, dependence on assisted feeding, premorbid undernutrition, without looking at the full range of factors or the different weights and their interaction specific to stroke patients. As a consequence there is no nutrition assessment tool for stroke (NATS) to guide best practice locally or nationally and practitioners currently rely on generic screening tools. The aim of the study is to identify the specific risk factors over a 9 month period. Following statistical analysis of the data, we hope to develop a nutrition assessment tool for stroke (NATS) to assess the risk of patients suffering from poor nutrition after a stroke.

Who can participate?
The study participants are those who have suffered an acute stroke and have then been transferred for inpatient rehabilitation at Feldon Stroke Rehabilitation Unit, Royal Leamington Spa Hospital, UK.

What does the study involve?
The study involves assessments over a nine month period.
Week 0: The patient is admitted to the Feldon Stroke Unit at the Royal Leamington Spa Rehabilitation Hospital.
Week 1: The patient will be approached within 1 week of admission to the unit, by a member of the research team/research assistant to discuss consent to participate in the research project (except those patients who lack the capacity to consent and who will not be included in the

study).
Week 1-2: Within 3 days of this discussion, if the patient agrees to participate in the study the researcher will gain their written consent.
Week 1-2: Within 1 week of written consent the interview research assistant to assess dependent variables (anthropometric data about nutrition status) and to review case notes and assess all independent variables.
Week 5-6: 4 weeks after the initial interview and assessment the dependent variables (anthropometric measurements) will be re-assessed by the research assistant. Those relevant independent variables (that might change over time will also be reassessed).
Week 9-10: 8 weeks after the initial interview assessment the dependent variables /anthropometrics and relevant independent variables will be re-assessed. Assessment may be in Feldon Stroke Unit or if discharged in the community setting.
Week 38-40: 9 months after admission to the rehabilitation stroke unit there will be a final assessment of dependent variables and relevant independent variables. By this time it very likely the participant will have been discharged from the unit, so the assessment will normally take place in the community setting where there are placed.

What are the possible benefits and risks of participating?
There will be no direct benefit or risk to study participants. It is hoped the findings will lead to a screening tool that will reduce the risk of poor nutrition following stroke and improve clinical practice regarding the specific needs of stroke patients in relation difficulties with nutrition.

Where is the study run from?
Feldon Stroke Unit at the Royal Leamington Spa Rehabilitation Hospital (UK).

When is the study starting and how long is it expected to run for?
June 2011 to September 2013

Who is funding the study?
Funding was by Coventry & Warwickshire Cardiovascular Network

Who is the main contact?
Mr Michael Church
michael.church@warkpct.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr Michael Church

Contact details
Royal Leamington Spa Rehabilitation Hospital
Heathcote Lane
Warwick
United Kingdom
CV34 6SR
+44(0)192 631 7700
michael.church@warkpct.nhs.uk

Additional identifiers

Study information

Scientific Title
Identification of factors affecting poor nutrition following acute stroke and the development of a nutrition assessment tool for stroke - NATS Study

Acronym
NATS Study

Study objectives
To identify which independent variables at what weighting and in what combination predict future nutrition status (dependent or outcome variable) in patients who have suffered an acute stroke, and have subsequently been transferred to a stroke rehabilitation ward.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Solihull, 17/05/2010, ref: 10/H1206/23, (AM03/1 Modified)

Primary study design
Observational

Study design
Prospective longitudinal study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Stroke

Interventions
In this study four widely accepted measures of nutritional status measures will be used:
1. Weight / weight change
2. Body mass index (BMI)
3. Triceps skinfold thickness (TST)
4. Mid upper-arm circumference (MUAC)

Using these outcome measures the main research question is, which of the following independent variables, with what weight and combination predict poor nutritional status:
1. Age
2. Sex
3. Diagnosis (type of stroke)
4. Side of lesion
5. Handedness
6. Hemiplegia (paralysis right/left)

7. Affected side (dominant or non-dominant)
8. Hemianopia (visual field defect present)
9. Number of previous strokes
10. Pre-stroke weight loss
11. Smoking (current smoker i.e. when acute stroke occurred)
12. Dysphagia (swallowing difficulty)
13. Receptive dysphasia (difficulty with understanding speech)
14. Expressive dysphasia (difficulty with producing speech)
15. Oral health
16. Neglect of one side when eating meals
17. Oobserved to require verbal or physical prompts to eat
18. Perceived depression
19. Perceived anxiety
20. Perceived taste
21. Perceived smell
22. Perceived nausea
23. Perceived pain
24. Perceived fatigue
25. Perceived appetite
26. Perceived thirst
27. Reduced decisional capacity

Based on the statistical analysis of this data, a second phase of the study will involve the development of a stroke specific screening tool, suitable for use in everyday clinical practice and evidence based.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Weight / weight change measures are done following admission at:
Week 1-2
Week 5-6
Week 9-10
Week 38-40

Key secondary outcome(s)
1. BMI
2. Triceps skinfold thickness
3. Mid upper-arm circumference
Measures are done following admission at:
Week 1-2
Week 5-6
Week 9-10
Week 38-40

Completion date
21/09/2013

Eligibility

Key inclusion criteria
1. Informed consent
2. Patient has a new acute stroke, is now medically stable, and has been admitted to Feldon Stroke Unit for inpatient rehabilitation
3. Sufficient English comprehension

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Lacks capacity to consent to participation in study
2. Under 18 years of age
3. Medically unstable
4. Patient Nil by Mouth
5. Patient has percutaneous endoscopic gastrostomy (PEG) prior to admission to Feldon Stroke Unit
6. Severe communication difficulties
7. Decline to participate

Date of first enrolment
21/06/2011

Date of final enrolment
21/09/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Leamington Spa Rehabilitation Hospital
Warwick
United Kingdom
CV34 6SR

Sponsor information

Organisation
NHS Warwickshire (UK)

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
Coventry & Warwickshire Cardiovascular Network (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration